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U.S. House of Representatives
COMMITTEE ON WAYS AND MEANS
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February 28, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

The nation is truly facing a public health and law enforcement crisis of historic proportions. While there are many significant policy decisions that may affect this crisis, we write to you today to bring your attention to a few recommendations that will strengthen efforts to address opioid overutilization and solicit additional information regarding CMS' efforts to stem the tide of this opioid epidemic.

From 2000 to 2015, more than a half million Americans died from opioid misuse – 33,000 in 2015 alone. Although overdose rates are highest for people 25 to 54, this public health emergency has had dramatic effects on Medicare beneficiaries.[1] In a recent report, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) found that in 2016, one-third of Medicare Part D beneficiaries filled an opioid prescription, and nearly 90,000 beneficiaries received "extreme" amounts of opioids that year.[2]

The Committee on Ways and Means has held two hearings exploring the ways the Medicare program can better serve Americans struggling with opioid use disorders. The first hearing, held by the Oversight Subcommittee on January 17, was entitled "The Opioid Crisis: The Current Landscape and CMS Actions to Prevent Opioid Misuse." This hearing included witnesses from the Government Accountability Office (GAO), OIG, and the Centers for Medicare & Medicaid Services (CMS). The second hearing, held by the Health Subcommittee on February 6, was entitled "The Opioid Crisis: Removing Barriers to Prevent and Treat Opioid Abuse and

[1] CDC. Understanding the epidemic: Drug overdose deaths in the United States continue to increase in 2015 2017 Available from: https://www.cdc.gov/drugoverdose/epidemic/index.html

[2] OIG. Opioids in Medicare Part D: Concerns about extreme use and questionable prescribing. 2017.

Dependence in Medicare." This hearing included Governor Phil Scott (R-VT), insurance officials from Aetna and WellCare, as well as a physician and an executive from treatment facilities for pain management and opioid use disorders.

The recommendations raised during testimonies in both hearings represent important steps your agency can and should take to continue responding to this national emergency. The proposed rule CMS published in November, entitled "CMS Proposes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-P)," represented a positive step in implementing some of the changes authorized under the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198). Specifically, CMS' proposed regulatory guidance on the implementation of the Medicare lock-in policy crafted by the Committee on Ways and Means is an important tool for protecting beneficiaries from opioid abuse and supporting those suffering from dependence.

Based on the feedback our committee received from experts over the course of our two hearings, we are writing to provide suggestions and solicit additional information regarding CMS' approach to implementing not only the lock-in policy but also other items we consider to be crucial to stemming the tide of this epidemic in a timely and effective manner. Specifically:

1. **Timeframe for Determining At-Risk Beneficiary**. CMS proposes that "a sponsor may not limit an at-risk beneficiary's access to coverage of frequently abused drugs to a selected prescriber(s) until at least six months has passed from the date the beneficiary is first identified as a potential at-risk beneficiary." The purpose of this program is to minimize harm to beneficiaries resulting from overuse of opioids. We respectfully request more information on how CMS determined six months to be the appropriate length of time. We further encourage CMS to consider each step and condense this timeframe without limiting or curtailing time for beneficiary appeals, notices, and other rights as described in the statute.

2. **Expanding Overutilization Monitoring System to Include Additional Drugs Susceptible to Fraud, Waste, and Abuse**. The OIG recommended that CMS and its Part D sponsors expand drug utilization reviews (DURs) to include some non-controlled drugs that are commonly used as opioid potentiators, increasing the risk of drug overdose from opioid use. While CMS concurred with the recommendation to expand DUR programs, noting the agency already encourages plan sponsors to examine non-opioids as part of those programs, CMS did not concur that it should similarly expand the Overutilization Monitoring System (OMS). Applying a wider lens to OMS more appropriately reflects the multiplicity of factors driving this epidemic and will ultimately ensure the agency more effectively protects beneficiaries and reduces abuse.

3. **Assessing Plan Sponsors' Actions in Response to Opioid Overprescribing.** CMS partners with Part D plan sponsors to monitor billing patterns and report abuse. Both OIG and GAO have identified this approach as an area of weakness within CMS' data systems, recommending that CMS require plan sponsors systematically report investigative activities and other actions taken around opioid overprescribing. Additionally, plans that report abuse cases to CMS are often times not made aware of the

actions CMS (through the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC)) has taken to address the situation – or their case is not addressed at all in certain circumstances – which creates an information gap and causes confusion among plan sponsors regarding which types of cases to refer. Currently, this lack of transparency has the potential to unnecessarily harm beneficiaries while yielding program integrity concerns. CMS should evaluate their current process to determine the best pathway for plans to share reports of abuse and determine what type of additional information from plans, if any, would be the most beneficial to curb opioid misuse.

4. **Encourage Plan Sponsors to Restrict Beneficiaries to a Limited Number of Pharmacies or Prescribers**. OIG recommended that CMS encourage Part D sponsors to establish lock-in programs, which are designed to identify beneficiaries at-risk for prescription drug abuse. Although CMS proposes allowing Part D sponsors the *option* of implementing lock-in programs, the agency should go a step further – by *encouraging* their widespread adoption across plans – as OIG recommended. Widespread utilization of lock-in programs is crucial for protecting Medicare beneficiaries from opioid use disorders.

5. **Special Enrollment Period for Beneficiaries Eligible for Low-Income Subsidies.** CMS has proposed that beneficiaries who are locked-in would no longer be eligible for the special enrollment period (SEP) that they would otherwise be able to use. We believe there should be an exceptions process for this forfeiture of SEP, particularly if a low-income subsidy (LIS) beneficiary is prescribed a new drug that is either not on the current plan's formulary or results in an increased copayment midyear. Given the financial constraints of this population, CMS should ensure that access to affordable, lifesaving drugs and Part D plans that best fit beneficiaries' needs is not hindered.

6. **Appeals.** Automatic escalation, as described by the statute in Section 1860D-04(c)(5)(E) of the Social Security Act, is a tool that would more quickly resolve issues and compress the timeline of resolving appeals. We recommend, consistent with legislative intent, that you ensure beneficiaries are aware of their right to appeal and the option of an automatic escalation to external review in an effort to compress the timeframe for action and ensure beneficiaries have quick resolution to issues that may arise.

7. **Four Pharmacy Test**. CMS has proposed using four pharmacies for frequently abused drugs to determine whether a beneficiary is potentially at-risk. How did CMS determine this number? What is the average number of pharmacies that Medicare beneficiaries use? Does this average number differ for beneficiaries who meet the CDC definition of overutilizing opioids?

8. **Pharmacists and Case Management.** Pharmacists are important links in the dispensing of Part D prescription drugs and serve as key access points for health information for Medicare beneficiaries when filling a prescription under Medicare Part D. We urge CMS to consider pharmacists as part of the Part D plan's case management for at-risk or potentially at-risk beneficiaries.

Given the severity of this crisis and the fact that both OIG and GAO have examined and reported gaps in CMS' system of monitoring opioid-related abuse, we request that the agency provide a detailed response by March 23, 2018, to the aforementioned comments and questions and continue to update the Committee on its progress. The lives of thousands of Americans are at risk – and we can only begin to develop sustainable solutions if we work together.

We look forward to your response to these crucial matters.

Sincerely,

Kevin Brady
Chairman
Committee on Ways and Means

Richard Neal
Ranking Member
Committee on Ways and Means

Peter Roskam
Chairman
Committee on Ways and Means
Subcommittee on Health

Sander Levin
Ranking Member
Committee on Ways and Means
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